

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
GREENEVILLE DIVISION**

UNITED STATES OF AMERICA and STATE
OF TENNESSEE,

Plaintiffs,

v.

WALGREEN CO.,

Defendant.

Case No. 2:21-CV-00080-JRG-CRW

ORAL HEARING REQUESTED

**WALGREEN CO.'S MOTION TO COMPEL
THE UNITED STATES' COMPLIANCE WITH ITS DISCOVERY OBLIGATIONS**

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Walgreens files this Motion to Compel because the United States has utterly and thoroughly refused to comply with its discovery obligations in this matter, even after this Court gave it additional time to so comply with the instruction that all parties move discovery forward quickly. Since that March 3, 2022 ruling and instruction by the Court, the United States has not produced a *single document* sought in discovery requests that Walgreens served on the government *up to nine months ago*. The United States' refusal to carry its burden in this matter is deeply troubling not only for its flagrant disregard of this Court's instructions, but more fundamentally for publicly accusing a party of fraud and then repeatedly and comprehensively depriving that party of information that will exonerate it. The deficiencies in the United States' discovery responses range from basic, discrete categories of information that are fundamental to any civil lawsuit and that should have been produced months ago, to larger categories of documents and information that it seems the United States still has not—nine months after Walgreens first served document requests—even begun to search and review. In sum, the United States has completely squandered the time this Court gave to it and has severely prejudiced Walgreens' ability to conduct discovery and defend itself in this matter. This Court should not countenance the United States' astonishing disregard of its discovery obligations and should order the United States to comply with its obligations immediately.

Nine months after receiving Walgreens' first discovery requests, and nearly four months after receiving Walgreens' most recent requests, the United States has absolutely failed to produce the following documents and information:

- *any* documents related to CMS Release No. 172;
- *any* emails—or even any information about how, if at all, it is searching for responsive emails;
- document preservation materials and information;

- the identities of individuals with knowledge of numerous relevant topics;
- materials from the United States’ case file on the Amber Reilly prosecution, which no longer enjoy law enforcement privilege protections because that case has concluded;
- documents related to claims audits for pharmacies;
- documents related to governmental policies for investigating and prosecuting civil cases involving alleged healthcare overpayments; and
- documents corresponding to the full range of Hepatitis C medications relevant to this case.

Walgreens now—not for the first time in this matter—faces looming deadlines that the United States’ intransigence is rendering impossible. As a matter of law and fairness, this Court should hold the United States to the same standard of compliance with discovery obligations as any other litigant. The United States’ brazen refusal to comply with its discovery obligations fundamentally impedes Walgreens’ right to fully defend itself on the merits against the United States’ allegations and is causing—and will continue to cause—substantial undue delay of the ultimate resolution of this case. Accordingly, this Court should grant this motion to compel.

I. BACKGROUND

On May 10, 2021, the United States and the State of Tennessee (collectively, the “government”) filed this action against Walgreens. The government alleges violations of the federal False Claims Act (“FCA”), the Tennessee Medicaid False Claims Act (“TMFCA”), and common law theories. *See* ECF 1. The government’s theory is premised on compliance with prior authorization criteria that the United States itself proclaimed in late 2015 to be contrary to federal Medicaid law. Indeed, so held Judge Jones in the Western District of Virginia when he *dismissed with prejudice* a related case arising out of the same substantive facts and alleging the same (or very similar) claims. *See* ECF 62. On March 3, 2022, Judge Jones denied the government’s motion for reconsideration. *See* Opinion and Order, *United States v. Walgreen Co.*, No. 1:21-

cv-00032-JPJ-PMS (W.D. Va.), ECF 49.¹ In this case, the government has argued that TennCare was not obligated to comply with federal Medicaid law because it received a waiver to operate as a “special demonstration project.” See ECF 42 at 6-8; *see also* ECF 1 ¶ 20 (Complaint alleges “TennCare operates as a special demonstration project authorized by the Secretary of the United States Department of Health and Human Services under the waiver authority conferred by 42 U.S.C. § 1315”).

Since the filing of the Complaint, Walgreens has repeatedly attempted to obtain discovery from the United States with virtually no success. Walgreens has served 64 RFPs and 25 interrogatories on the United States. See Exs. A through E to Declaration of Michael R. Dziuban (“Dziuban Decl.”) submitted herewith.² The United States has provided limited and deficient interrogatory responses, made *a single limited* document production, and, despite a series of written and oral meet-and-confer communications over the last several months, has refused to make additional productions to fulfill its obligations. See Exs. F through I. Fact discovery is currently scheduled to close on June 27, 2022, to be followed by expert discovery. ECF 97 at 2. Before the fact discovery cutoff, the parties still need to conduct depositions, which will require the government to first complete its interrogatory responses and document productions. In fact, Walgreens already has been forced to postpone several depositions because of the government’s failure to produce necessary documents. Walgreens is now back to facing an inequitable choice: (1) move forward with depositions without the benefit of documents in order to meet the Court’s deadlines, while potentially losing the ability to question witnesses on documents if and when they are produced; or (2) risk being barred from taking depositions at all if the United States is allowed

¹ The United States filed a notice of appeal on May 1; on May 2, the Commonwealth of Virginia followed suit.

² Exhibits are attached to the Dziuban Declaration.

to run out the clock without completing its interrogatory responses and document productions. Dispositive motions are currently due by September 15, 2022. *Id.* These and other case deadlines necessitate the United States' prompt compliance with its discovery obligations.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 26 allows very broad discovery. *See Easterly v. Thomas*, 2022 WL 256284, at *2 (E.D. Tenn. Jan. 26, 2022) (Greer, J.). "Under Rule 37 of the Federal Rules of Civil Procedure, 'a party may move for an order compelling disclosure or discovery,' provided that the party certify that it 'has in good faith conferred or attempted to confer with the person or party failing to make disclosure in an effort to obtain it without court action.'" *Appalachian Reg'l Healthcare, Inc. v. U.S. Nursing Corp.*, 2017 WL 9690401, at *1 (E.D. Ky. Sept. 1, 2017) (citing Fed. R. Civ. P. 37(a)(1)). "[A]n evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond." Fed. R. Civ. P. 37(a)(4). "[P]arties cannot be permitted to jeopardize the integrity of the discovery process by engaging in halfhearted and ineffective efforts to identify and produce relevant documents." *Allstate Ins. Co. v. Papanek*, 2019 WL 6698342, at *10 (S.D. Ohio Dec. 9, 2019) (citation and internal quotation marks omitted).

III. ARGUMENT

The United States' refusal to cooperate in discovery takes the form of a combination of improper relevance objections, overbroad and misplaced claims of privilege, and simple outright failure to produce documents it has no excuse not to produce. No matter what form the deficiencies take, they all are prejudicing Walgreens, and as a matter of law they all demand this Court's intervention.

A. The United States Has Improperly Withheld Relevant Documents Related to CMS Release No. 172 and the Alleged “Waiver” Upon Which the Government Relies

The United States has improperly withheld documents relating to a very significant release issued by the United States Centers for Medicare and Medicaid Services (“CMS”) in 2015. CMS is the federal agency within the United States Department of Health and Human Services (“HHS”) that partners with states to administer the Medicaid program under the requirements of the federal Medicaid Act, 42 U.S.C. § 1396 *et seq.* In Release No. 172, CMS warned states that the prior authorization criteria upon which the United States is now relying to pursue its fraud claims here—specifically, minimum fibrosis scores and history of sobriety—were unlawful. Because the prior authorization criteria were unlawful, the misrepresentations the government alleges in this case could not, by definition, have been material, as Judge Jones correctly held in dismissing the government’s substantially identical claims in the Western District of Virginia. *See* ECF 62. Even if the United States disagrees with that position in this case, that disagreement does not permit it to withhold documents relevant to Walgreens’ defenses.

1. CMS Release No. 172 and the Alleged CMS Waiver Are Relevant

In this case, unlike in the Western District of Virginia, the government is relying on what the government says is an HHS waiver of the Social Security Act’s legal requirements. Walgreens has every right to challenge the government’s position and develop facts relevant to the application of Release No. 172 to the prior authorization criteria and the government’s contemporaneous understanding of the legality of those criteria. And, having broadly alleged in its Complaint (and subsequently in motions practice before this Court) that the State received a waiver of Social Security Act requirements, the United States cannot now prevent Walgreens from taking discovery probing those allegations. Obtaining that discovery from the United States in particular is critical given the joint federal/state nature of the Medicaid program and the supremacy of federal law in

the Medicaid framework. With both U.S. and Tennessee funds flowing to TennCare in the relevant period, and with both sovereigns seeking remedies in this case, the materiality *vel non* of certain prior authorization criteria to the federal government is fundamental to Walgreens' ability to defend itself against the allegations in this case.

Despite Walgreens' repeated requests for information and documents relating to CMS Release No. 172 and the government's waiver defense, the United States has agreed to produce only a narrow set of documents: "communications with TennCare related to Release No. 172" (none of which it has produced to date) and documents that are already publicly available. Thus, by way of example only, the United States has refused to produce CMS internal communications regarding Release No. 172 and the review and approval of TennCare's "special demonstration" status. The United States' objections to producing any additional information are all meritless.³

First, in response to Walgreens' motion to dismiss in light of CMS Release No. 172, the United States argued that dismissal would not be appropriate without "factual development." *See*

³ Walgreens' RFP 58 seeks documents and communications relating to the promulgation and implementation of Release No. 172; RFP 59 seeks CMS documents and communications pertaining to the criteria considered or used by state Medicaid programs, including TennCare, for coverage for Hepatitis C medications (including whether such criteria were consistent with the Social Security Act); RFP 60 seeks documents relating to TennCare's application to operate as a special demonstration project under the Secretary of Health and Human Services' waiver authority; and RFPs 61 and 62 seek, respectively, information relating to the cost effectiveness of the four direct-acting antivirals ("DAAs") and communications among the Plaintiffs and the State's pharmacy benefits managers ("PBMs") relating to DAA coverage requirements. Ex. C at 12-14. Numerous other RFPs implicate CMS Release No. 172 and the supposed CMS "waiver," and have met with a similar combination of misplaced privilege objections, overly narrow—or sometimes even nonexistent—written responses, and woefully deficient document productions on the part of the United States. *See, e.g.,* Ex. J at 7-9 (RFPs 5, 7, 8, and 9 (dealing with the TennCare PDL and TennCare's prior authorization requirements for Hepatitis C drugs)); Ex. K at 7-8 (RFPs 34 and 35 (dealing with the Four DAAs' clinical advantages and access to those drugs by TennCare enrollees)); *Id.* at 8-10 (RFPs 37, 38, 39, and 40 (dealing with CMS's Hepatitis C Affinity Group, including any efforts by that body to "increase access by TennCare beneficiaries to the Four DAAs or to Other DAAs"))).

ECF 38 at 2 (asking the Court not “to interpret [Release No. 172] without context, fact development . . . as if it were a final agency action or a matter of law.”). The United States cannot now seriously be heard to protest that discovery relating to CMS Release No. 172 is either unexpected or irrelevant.

Second, the United States has waived all objections on relevance grounds. Most significantly, the Complaint itself preemptively alleges that TennCare operates as a “special demonstration project” under “waiver authority” exercised by the federal government. ECF 1 ¶ 20. A defendant is entitled to take discovery into the allegations in a plaintiff’s complaint. Until recently, the United States acknowledged the relevance of CMS Release No. 172 and agreed to produce some related documents. For example, during a September 27 meet-and-confer—*over seven months ago*—both the United States and the State said they were not asserting that documents relating to Release No. 172 are categorically irrelevant. Ex. H at 7. To that end, the United States answered several interrogatories relating to CMS Release No. 172, acknowledging its relevance. *See* Ex. J at 8-11 (responses to Interrogatories 7, 9, 10, 11, 12, and 13). Basic discovery principles dictate that the United States continue responding to requests related to CMS Release No. 172 and the alleged CMS waiver, given these concessions and the government’s own affirmative allegations.

Third, even setting aside the United States’ waiver of any relevance objection, the documents the United States is withholding relating to CMS Release No. 172 plainly *are* relevant. “[A] request for discovery should be considered to be seeking relevant information if there is *any* possibility that the information sought may be relevant to the claim or defense of any party in the action.” *Invesco Institutional (N.A.), Inc. v. Paas*, 244 F.R.D. 374, 380 (W.D. Ky. 2007). “When the discovery material sought appears to be relevant, the party who is resisting production has the

burden to establish that the material either does not come within the scope of relevance or is of such marginal relevance that the potential harm resulting from production outweighs the presumption in favor of broad disclosure.” *Odello Indus., LLC v. Sherwin-Williams Co.*, 2015 WL 13413519, at *2 (E.D. Tenn. May 22, 2015) (citation and internal quotation marks omitted). Here, the relevance of CMS Release No. 172 and related documents is glaring. The release is an *admission by a party-opponent, the United States*, that the prior authorization criteria on which the government now relies are *invalid under federal Medicaid law*. Refusing discovery related to Release No. 172 on relevance grounds is like saying that the speed limit is not relevant to a speeding ticket case. It just makes no sense.

Having put the waiver at issue *itself* in the Complaint, the United States has asserted that CMS’s purported waiver of TennCare’s compliance with the requirements of Section 1927 of the Social Security Act precludes the discovery Walgreens seeks. Walgreens certainly *is* permitted to take discovery of the government’s alleged basis for the false claims and the supposed waiver, however. Moreover, the United States’ position is illogical: on the one hand, the government claims that TennCare did not need to comply with Section 1927’s statutory requirement; on the other hand, the United States issued Release No. 172 directing the states to comply with Section 1927. In light of this facial inconsistency, Walgreens must be permitted to take discovery into the scope and effect that CMS intended both the waiver and Release No. 172 to have. Moreover, the government’s position on waiver contradicts the requirement that a special demonstration project “assist in promoting the objectives of” the Medicaid program. 42 U.S.C. § 1315(a).⁴ To test the

⁴ This requirement is reflected in CMS’s criteria for evaluating applications for special demonstration project status, including whether a proposed demonstration will “[i]mprove health outcomes for” and “[i]ncrease and strengthen overall coverage of low-income individuals in the state.” Dep’t of Health & Human Servs., First Report on Section 1115(a) Demonstrations: *(Cont’d on next page)*

United States' argument that limits on access to these curative drugs were proper, Walgreens must be able to take discovery on the internal process by which CMS evaluated and approved TennCare's special demonstration project application, including internal communications in the course of that process that relate to or address the inconsistencies outlined above.

2. The United States Has Improperly Relied on a Blanket Assertion of the Deliberative Process Privilege

The United States improperly invoked the deliberative process privilege, and it certainly cannot rely on a blanket assertion of privilege. The United States has not produced a privilege log asserting the privilege over any specific documents, nor has it met its burden of establishing that the privilege applies. *Pub. Emps. for Envtl. Responsibility v. E.P.A.*, 213 F. Supp. 3d 1, 15 (D.D.C. 2016) (“A general statement . . . is not sufficient to carry the [government’s] burden to explain the function and significance of a document in the [government’s] decisionmaking process.”). The application of the deliberative process privilege is “dependent upon the individual document and the role it plays in the administrative process,” *Coastal States Gas Corp. v. Dep’t of Energy*, 617 F.2d 854, 867 (D.C. Cir. 1980), and should be construed as “narrowly as consistent with efficient Government operation.” *Dep’t of Treasury v. PBGC*, 222 F. Supp. 3d 38, 42 (D.D.C. 2016) (citation and internal quotation marks omitted). Without a privilege log that the United States has had *nine months* to prepare and produce, any such claim is premature.

Even if the deliberative process privilege were to apply to certain documents, it would be improper to categorically withhold responsive documents on the basis of privilege. The deliberative process privilege protects predecisional and deliberative documents. *Parke, Davis &*

Transparency in the Review and Approval of Medicaid and Children’s Health Insurance Program (CHIP) Section 1115 Demonstrations, 11-12,
<https://www.medicaid.gov/medicaid/downloads/1115-transparency-rtc.pdf>.

Co. v. Califano, 623 F.2d 1, 6 (6th Cir. 1980). “Predecisional” means a document that “came into being before” the relevant decision. *Id.* To be “deliberative,” a document must “truly reflect the deliberative or policy making processes of an agency,” rather than contain “purely factual, investigative” information unless that information is “inextricably intertwined with policymaking processes.” *Id.* at 5 (citations and internal quotation marks omitted).

Here, none of Walgreens’ requests categorically seek predecisional or deliberative documents subject to the deliberative process privilege. For example, RFP 58 seeks (among other things) “research memoranda” and “medical studies” underlying Release No. 172. Ex. C at 12-13. Such documents are not invariably predecisional or deliberative. *Parke, Davis*, 623 F.2d at 6 (“[U]nless the opinion of an expert somehow reflects the deliberative process of decision or policy making, the opinion [itself] does not come within the exemption.”). And, of course, if there were responsive documents post-dating Release No. 172, they would be post-decisional and therefore not privileged. *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 151-52 (1975). Post-decisional internal communications that explain the rationale or thought process behind a policy decision are not shielded from discovery by the deliberative process privilege. *Id.* at 152 (“communications made after [a] decision and designed to explain it” are not protected by the deliberative process privilege).

In addition, “straightforward explanations of agency regulations in specific factual situations” are not deliberative because “[n]o ‘decision’ is being made or ‘policy’ being considered.” *Coastal States*, 617 F.2d at 868. Accordingly, “[a] document that does nothing more than explain an existing policy cannot be considered deliberative.” *Pub. Citizen, Inc. v. OMB*, 598 F.3d 865, 876 (D.C. Cir. 2010); *see also Nat’l Day Laborer Org. Network v. United States*, 811 F. Supp. 2d 713, 741 (S.D.N.Y. 2011) (“Deliberations about how to present an already decided policy

to the public, or documents designed to explain that policy to—or obscure it from—the public, including in draft form, are at the heart of what should be released[.]”).

Similarly, Walgreens’ RFP 59 requests *post*-decisional and/or *non*-deliberative documents, such as analyses of “whether the [coverage] criteria” at issue “did or could result in the denial of coverage to Medicaid beneficiaries seeking any medically necessary drug for an FDA-approved indication.” Ex. C at 13. So too with Walgreens’ RFP 60, which requests (among other things) documents relating to “CMS’s decisions to grant TennCare’s applications” for special demonstration project status and documents related to “the evaluations and considerations underlying those decisions.” *Id.* at 13-14. While predecisional deliberative documents might be privileged, post-decisional documents explaining CMS’s decisions and the rationales for them are by definition not privileged. *Sears, Roebuck*, 421 U.S. at 151-52.

In short, the United States should be compelled to make complete productions of all responsive documents relating to Release No. 172 and the alleged waiver as a special demonstration project. If the United States intends to assert that any individual documents are privileged, the United States should identify those specific documents and describe them in sufficient detail in a privilege log so that Walgreens (and the Court) can assess the merits of the objection. Given the extensive delays that the United States has already caused on this matter, Walgreens requests that this Court order the United States to make complete document productions no later than one week after the entry of an order granting this Motion.

B. The United States Has Failed to Provide Basic Information About Its Email Searches and It Has Failed to Honor Its Obligations to Produce Relevant Emails

The United States has failed to produce basic information about its email searches, and to honor its obligations to produce relevant emails. These failures are so extensive, repetitive, and inexplicable that it now appears the United States is intentionally shirking its duties. Walgreens

served its first document requests nine months ago, yet the United States has failed to produce a single responsive email.

Accordingly, the Court should compel the United States immediately to produce: (1) a list of custodians to be searched, and (2) the results of searches using the terms provided by Walgreens seven months ago. Moreover, this Court should compel the United States to begin producing responsive emails right away on a rolling basis to be completed within one week.

C. The United States Has Improperly Withheld Relevant Documents and Information Regarding Document Preservation

1. Walgreens' Interrogatory Concerning the United States' Implementation Of a Document Hold

Claiming attorney-client and work-product privileges, the United States improperly refused to provide information in response to Interrogatory 15 seeking the existence, timing, and basic details of any document holds implemented in this case. *See* Ex. F at 14. To the extent the United States argued that it does not have to produce such information unless Walgreens shows relevant information has been lost or destroyed, that argument is misplaced.⁵

First, the United States' privilege objection is meritless. Although litigation holds can be privileged or protected by the work product doctrine under narrow circumstances, those privileges do not protect from disclosure *the facts* underlying a particular communication or document. For

⁵ The United States did not object on relevance grounds. Information regarding document preservation is plainly relevant to this case in light of the United States' Reverse FCA allegations. As Walgreens explained at length in its motion to dismiss the Complaint, reverse false claims liability on the basis of "knowing[] and improper[] avoid[ance]" of a repayment obligation requires that the government (including the United States) have been deceived by the defendant's conduct. *See* ECF 17 at 16-18 (heading altered). Here, the United States was not deceived because it knew of the alleged conduct before Walgreens did. *See id.* Taking discovery on what the United States knew and when it knew it is critical to Walgreens' ability to prove that the United States was not deceived by Walgreens in the course of the government's investigation. That, in turn, requires knowing what information exists and/or may have been lost or destroyed that is relevant to the United States' knowledge.

that reason, there is no privilege over “the circumstances of a company’s litigation hold,” or over “what kinds and categories of ESI [the company’s] employees were instructed to preserve and collect, and what specific actions they were instructed to undertake to that end.” *EPAC Techs., Inc. v. HarperCollins Christian Publ’g, Inc.*, 2018 WL 3342931, at *2 (M.D. Tenn. Mar. 29, 2018) (citations and internal quotation marks omitted) (listing cases where discovery was permitted without a preliminary finding of spoliation). Here, as in that case, Walgreens seeks only information regarding the facts and circumstances surrounding the steps the United States took to preserve documents, not communications between the United States and potential document custodians regarding their preservation obligations, work product prepared in anticipation of litigation, or opinion work product in the form of attorneys’ mental impressions. Such “facts and circumstances” information is not privileged or protected in the first place, and therefore the government cannot withhold it on that basis. *Id.* at *2-4; *In re Columbia/HCA Healthcare Corp. Billing Practices Litig.*, 293 F.3d 289, 294 (6th Cir. 2002) (making clear that opinion work product is “any material reflecting the attorney’s mental impressions, opinions, conclusions, judgments, or legal theories.” (citation and internal quotation marks omitted)).

Information concerning a party’s preservation efforts “becomes especially relevant where the adequacy of a party’s preservation efforts is in question.” *HarperCollins*, 2018 WL 3342931, at *2-4. Here, the adequacy of the United States’ preservation efforts is squarely in question given the juxtaposition between (1) its failure to provide plainly non-privileged information regarding its document hold, on one hand; and (2), on the other hand, the State’s interrogatory responses reflecting that TennCare did not implement a litigation hold until mid-May 2021, *nearly five years after* the investigation preceding this litigation commenced and approximately four and a half years after Reilly pled guilty. Ex. L at 19. Moreover, the United States’ failure to take adequate steps

to preserve CMS documents has resulted in sanctions against the government before in at least one federal FCA case. *See United States ex rel. Baker v. Cmty. Health Sys., Inc.*, 2012 WL 12294413, at *17 (D.N.M. Aug. 31, 2012) (imposing spoliation sanctions on the United States “for its failure to issue a timely and an adequate litigation hold,” where relator filed complaint in late 2005 and government did not implement a hold until February 2009), *report and recommendation adopted*, 2012 WL 5387069, at *1 (Oct. 3, 2012).

In short, Walgreens simply seeks basic information about the facts and circumstances of the United States’ litigation hold. That information is discoverable and not privileged. *HarperCollins*, 2018 WL 3342931, at *2. Accordingly, the Court should compel the United States to answer Interrogatory 15 no later than one week after the entry of an order granting this Motion.

2. The United States’ Other Deficiencies in Preservation-Related Discovery

The United States has failed to produce discovery responsive to RFPs and interrogatories seeking documents and additional information relating to preservation, including information on the United States’ document retention policies and practices. In particular, the government has objected wholesale to responding to RFPs 43-45, 47-53, and 56; and Interrogatories 17-21, 23, and 25. The United States’ objections on relevance, overbreadth, and privileges are meritless. *See* Ex. M at 7-12; Ex. G at 4-8.⁶ Walgreens is not seeking copies of litigation hold memoranda or other privileged communications related to preservation. Instead, Walgreens is seeking, among other things, documents and information regarding the facts and circumstances of the United States’

⁶ While Walgreens disputes the United States’ overbreadth objections to these requests and reserves the right to bring that issue to the Court’s attention at a later date, at present Walgreens is prepared to work with the United States to confirm the precise scope of the materials Walgreens is seeking such that any overbreadth objections can be addressed.

consideration of whether and when to implement a litigation hold, of the implementation of that hold, and of the scope and application of the hold itself.

The United States' relevance and privilege objections fail for the same reasons set forth above. *See supra* Section III.C.1. The privilege and work product objections are misplaced given that many of the requests seek policies and procedures promulgated in the ordinary course of agency business. Such documents are not privileged communications or work product. *See United States v. Roxworthy*, 457 F.3d 590, 593-94 (6th Cir. 2006) (“[A] document will not be protected [by the work product doctrine] if it would have been prepared in substantially the same manner irrespective of the anticipated litigation.”); *Ross v. Abercrombie & Fitch Co.*, 2008 WL 728329, at *5 (S.D. Ohio Mar. 14, 2008) (directing company to produce documents reflecting its document retention policy because they were not protected by the attorney-client privilege).

The United States' deliberative process objections are also groundless. Again, the deliberative process privilege protects documents that are predecisional and deliberative. *Parke, Davis*, 623 F.2d at 6; *supra* at 9. The United States' broad objections to Walgreens' discovery requests take a sledgehammer to these fundamental principles. First, the United States has failed to submit a privilege log describing the alleged privileged documents, which is essential to carry its burden to establish that the documents are in fact privileged. Second, certain requests plainly seek only post-decisional documents. For example, RFP 44 seeks documents “reflecting any other *policy, procedure, or practice* related to document management, storage, or preservation.” Ex. C at 4 (emphasis added). Nothing about that request includes predecisional materials. Insofar as other RFPs seek documents related to policies and procedures for determining whether to implement, and for implementing, document holds in various types of cases, the requests simply seek documents that reflect or apply such policies and procedures. Indeed, for the privilege to

apply, the policies must be both predecisional and deliberative, and they must relate to a “significant *policy* decision.” See *Petroleum Info. Corp. v. Dep’t of Interior*, 976 F.2d 1429, 1437 (D.C. Cir. 1992). Agency policies regarding document holds are not a “significant policy decision” subject to the protections of the deliberative process privilege.

In short, the Court should compel the United States to produce, within two weeks of an order granting this Motion, any non-privileged, responsive materials and information. The Court should also compel the United States to produce a detailed privilege log concerning documents withheld on grounds of any applicable privilege.

D. The United States Has Improperly Delayed Responding to Interrogatories Seeking Identities of Individuals with Relevant Information

Interrogatory No. 3. The United States improperly objected on work product grounds to Walgreens’ request to “[i]dentify all persons who assisted in the preparation of any of the answers to these Interrogatories, and for each such person, identify the particular Interrogatory answer(s) or portion(s) thereof with which the person assisted.” Ex. F at 5. Walgreens subsequently offered to narrow this request to seek only “the identities of all persons ultimately responsible for the information provided in the United States’ responses” to the interrogatories. Ex. I at 4. The United States failed to respond to that offer, and its continued objection to the narrowed request lacks merit.

The work product doctrine does not protect the identities of the individuals ultimately responsible for the information provided in the United States’ responses to Walgreens’ interrogatories, just as there is no privilege or work-product protection for the identities of individuals engaged in privileged communications. Responding to the modified interrogatory does not require the United States to disclose fact work product in the form of documents or tangible things. Nor does it require the United States to divulge opinion work product, because the identity

of a person responsible for a particular piece of information does not reveal the identity of all persons whom the United States approached or considered approaching in an effort to obtain that information. *Compare Bose v. Rhodes Coll.*, 2017 WL 4479258, at *9 (W.D. Tenn. Oct. 6, 2017) (denying motion to compel response to interrogatory seeking identities of persons who helped prepare other interrogatory responses, because such request was “tantamount to a request for a list of individuals whom [the responding party] interviewed,” which the court deemed to be work product). At the same time, the information is necessary to Walgreens’ defenses and its ability to take further discovery from the government, and the information is not readily obtainable from another source. The need is particularly pronounced given that counsel for the United States himself verified both sets of responses to Walgreens’ interrogatories, leaving Walgreens completely in the dark as to who within CMS (for example) is ultimately responsible for the information counsel gathered and produced. The United States should be compelled to answer Interrogatory 3, as modified.

Interrogatories Nos. 4 and 5. Walgreens seeks information regarding persons affiliated with HHS and DOJ who reviewed relevant prior authorization documents and/or claims for payment. *See* Ex. D at 11. The United States, in relevant part, objected to these interrogatories on: (1) work product grounds; (2) deliberative process grounds; and (3) an assertion that any information the United States provided to Walgreens “pertaining to those reviews” prior to the filing of the Complaint is subject to Federal Rule of Evidence 408. Ex. F at 5-6. None of these objections has merit.

As to the first objection, Walgreens seeks information about reviews conducted in the ordinary course of government business after the time of the documents’ submission. These documents were not prepared in anticipation of litigation and therefore are not protected by the

work product doctrine. Fed. R. Civ. P. 26(b)(3), Advisory Committee’s Note to 1970 Amend, (“Materials assembled in the ordinary course of business . . . are not under the qualified immunity provided by this subdivision.”); *Plate, LLC v. Elite Tactical Sys., LLC*, 2020 WL 5209303, at *15 (E.D. Tenn. Sept. 1, 2020) (same). As to the deliberative process objection, the United States’ position suffers from the same defects outlined above in Section III.B. And as to the third objection, Rule 408 governs admissibility, not discoverability, *see* Fed. R. Evid. 408, so the United States’ responses were deficient even if responsive documents might be inadmissible under Rule 408. The Court should compel the United States to amend its responses to Interrogatories 4 and 5.

Interrogatory No. 8. The United States refused to respond to a request for information regarding the identities of persons with knowledge concerning federal financial participation in TennCare under the Medicaid program. Ex. F at 8-9. This is elementary information given the shared state-federal nature of the Medicaid program. The United States objected to this interrogatory on the basis that it is “vague, ambiguous, overly broad, unduly burdensome and incapable of a meaningful response,” and did not provide information regarding the identity of any person with the referenced knowledge. *Id.* Despite agreeing to reconsider its response after Walgreens provided examples of the types of information it is seeking, the United States still has not amended its response. The United States should have no difficulty conferring with CMS and other entities to determine who set the parameters for the federal government’s involvement in reviewing, funding, assisting, evaluating or otherwise participating in TennCare’s prescription drug benefit. That information is essential to Walgreens’ ability to depose relevant witnesses and seek relevant documents.

This Court should compel the United States to amend its responses to Interrogatories 3, 4, 5, and 8 by no later than two weeks after the entry of an order granting this Motion.

E. The United States Has Improperly Refused Production of the Reilly Case File

Next, the United States has improperly refused to produce documents related to its criminal prosecution of Reilly in the case *United States v. Reilly*, No. 2:16-cr-00107-JRG. Ex. J at 6. The United States' entire claim of fraud is predicated on the conduct of Reilly and her subsequent criminal prosecution. Despite this, to date the United States has not produced a single document that Walgreens did not already have access to, as it chose to produce only Reilly's personnel file (which Walgreens already has) and plea agreement (which is a matter of public record). *Id.* Walgreens has also asked for the presentence report and psychological report that were prepared in connection with the Reilly case. Ex. H at 4. Although the United States initially agreed, it then informed Walgreens that it had located Reilly's presentence report but was assessing under what conditions it could be produced, apparently out of confidentiality concerns. That was nearly *seven months ago*, with no follow-up by the United States. Ex. N at 1-2. The government has not made any other objections to the production of these documents, and whatever confidentiality concerns the United States may have can be addressed via the Protective Order in this case or an appropriate supplemental protective order. There simply is no justification for the United States to drag its feet in producing such basic, readily accessible documents, and the Court should order their production immediately.

More broadly, the United States objected to the production of the Reilly case file on attorney-client privilege, work product, and law enforcement privilege grounds. *See* Ex. J at 6. Yet, to date, the United States has not produced a privilege log that would allow Walgreens to assess these claims with the level of detail that the Federal Rules require. Even so, it simply cannot be right that the entire contents of the investigation file are privileged or protected. While certain

types of documents such as interview notes and internal communications might be properly withheld if they were to meet the elements of one or more privileges, other types of documents are plainly not protected—such as communications between the United States and Reilly, communications between the United States and other Walgreens personnel (such as Brianna Brock), materials received from third parties, and communications with third parties.

When it comes to the law enforcement privilege in particular, the United States is woefully far from having asserted the privilege, much less established that it applies here. In order to show that the law enforcement privilege applies, the United States must put forth a “formal claim of privilege by the head of the department having control over the requested information,” that “assertion of the privilege must be based on actual personal consideration by that official,” and “the information for which the privilege is claimed must be specified, with an explanation why it properly falls within the scope of the privilege.” *Metris-Shamoon v. City of Detroit*, 335 F.R.D. 387, 391-92 (E.D. Mich. 2020) (citations and internal quotation marks omitted). Here, the United States has not even attempted to satisfy a single one of these requirements. Nor could it. “The purpose of the law enforcement privilege is to prevent disclosure of law enforcement techniques and procedures, to preserve confidentiality of sources, to protect witness and law enforcement personnel, to safeguard the privacy of individuals involved in an investigation, and otherwise to prevent interference with an investigation.” *Id.* at 392 (citations and internal quotation marks omitted). But the privilege “shields only suggestions, advice, recommendations, and opinions, rather than factual and investigatory reports, data and surveys in government[] files.” *United States v. Leggett & Platt, Inc.*, 542 F.2d 655, 660 (6th Cir. 1976). And where, as here, an investigation has been complete for nearly five years and follow-on civil litigation is significantly underway, the risks of interference with a government investigation, and of jeopardizing the

secrecy of government sources of information, are insignificant at best, if not altogether moot. *See id.* at 659 (“[T]here is less government interest in secrecy in completed, than in ongoing, investigations.”). The United States’ cavalier invocation of the law enforcement privilege flies in the face of established law on the subject.

The Court should compel the United States to produce, within two weeks of an order granting this Motion, any non-privileged, responsive materials and information. The Court should also compel the United States to produce a detailed privilege log concerning documents withheld on grounds of any applicable privilege.

F. The United States’ Discovery Responses Regarding Claims Audits and the Conduct of Investigations Related to Medicaid Overpayments Are Deficient

The United States has improperly failed to produce documents in response to RFP 16, which seeks documents reflecting any audits concerning pharmacies’ claims for payment for prescriptions of the Four DAAs relevant to this case, despite agreeing to produce such documents relating to the Kingsport, Tennessee pharmacy at issue in this case. Ex. J at 11-12.

The United States’ response to RFP 17 is similarly deficient. This RFP seeks information regarding the effects on regulated entities of legal provisions requiring the reporting and returning of overpayments made by any federal or state healthcare program, including effects related to actions or investigations brought under the FCA and the TMFCA, in an effort to obtain information Walgreens will use to argue that the United States’ reverse false claims theory in particular is inconsistent with the statute itself. Ex. A at 10.⁷ The United States first incorrectly objected to

⁷ Relatedly, Walgreens’ RFP 63 seeks all communications within the government, or between the government and Magellan, “reflecting or relating to any attempt to identify or quantify the overpayments Plaintiffs allege in the Complaint.” Ex. C at 14. The United States objected wholesale on privilege grounds alone. Ex. M at 16. Walgreens assumes that means that no non-privileged communications exist that are responsive to the request. Of course, without a privilege
(*Cont’d on next page*)

Walgreens' request for documents from 2010 through the present, and sought instead to produce only documents from the October 2014 – June 2016 timeframe. But internal policy developments concerning the investigation and pursuit of Reverse FCA and Reverse TMFCA cases are not relevant merely to the extent they occurred between October 2014 and June 2016. For example, to the extent that the government's policies during that period were formulated prior to October 2014, related documents are relevant to the subsequent application of those policies. The Court should compel the United States' production of documents in response to RFPs 16 and 17.

G. The United States Has Refused to Agree to Reasonable Parameters Regarding the Scope of Responsiveness as Related to Other Hepatitis C Drugs

The United States has incorrectly taken the position that information related to Hepatitis C medications other than the Four DAAs is irrelevant to this litigation.⁸ Showing relevance in discovery is “an extremely low bar.” *In re Ford Motor Co. Spark Plug & 3-Valve Engine Prods. Liab. Litig.*, 98 F. Supp. 3d 919, 925 (N.D. Ohio 2014). Discovery regarding Hepatitis C medications other than the Four DAAs is critical to Walgreens' ability to make its arguments related to Release No. 172, by determining the views that TennCare and CMS took of the clinical superiority of the Four DAAs compared to other Hepatitis C drugs. *See* 42 U.S.C.

log from the United States, Walgreens cannot assess whether the United States' blanket privilege objection actually holds true when it comes to specific communications.

⁸ This deficiency affects RFPs 5, 32, 33, 40, and 62. *See* Exs. A, B, and C. Walgreens and the government are conferring in an effort to limit the scope of RFPs 7, 8, 9, and 10, which also implicate drugs other than the Four DAAs. The United States also has refused to produce information from outside the October 2014 to December 2016 period cited in the Complaint, which information is necessary to account for the fact that Hepatitis C DAAs began to receive FDA approval in or around 2011, and that TennCare therefore likely began crafting its prior authorization criteria around that time. It is critical that Walgreens be able to trace that process comprehensively in order to mount its defense that TennCare's prior authorization criteria were invalid (and therefore immaterial) because they were inconsistent with the Relevant Drugs' clinical advantages. Walgreens and the government are in the process of conferring about narrowing the relevant period for certain RFPs that implicate these timeframe issues, and Walgreens is optimistic that an agreement can be reached with the government in this regard.

§ 1396r-8(d)(4)(C) (prohibiting exclusion of drugs that “have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome . . . over other drugs”). The Court should compel the United States to produce responsive documents related to all Hepatitis C medications.

IV. CONCLUSION

For the foregoing reasons, Walgreens respectfully moves this Court for an order directing the United States to do the following:

1. Make complete productions of all responsive documents related to Release No. 172 and the TennCare Waiver, by no later than seven days after the entry of an order granting this Motion;
2. immediately produce information to Walgreens regarding the United States’ document search and collection efforts, including the hit counts for Walgreens’ search terms and a complete list of custodians whose documents have been searched;
3. produce emails to Walgreens on a rolling basis, to be completed by no later than seven days after the entry of an order granting this Motion;
4. answer Interrogatory 15 no later than seven days after the entry of an order granting this Motion;
5. amend its responses to Walgreens’ other interrogatories related to document preservation, and produce all responsive, non-privileged documents in response to Walgreens’ RFPs related to document preservation, by no later than 14 days after the entry of an order granting this Motion;
6. amend its responses to Interrogatories 3, 4, 5, and 8 no later than 14 days after the entry of an order granting this Motion;
7. produce the Reilly case file within 14 days of an entry of an order granting this Motion;
8. produce documents immediately in response to RFPs 16 and 17;
9. produce a privilege log; and
10. apply the Hepatitis C medication parameters set forth in Walgreens’ discovery requests, rather than the narrower parameters reflected in the United States’ responses and objections to the requests.

In addition, Walgreens requests that this Court require the government to cover all costs Walgreens incurred in making this motion. *See* Fed. R. Civ. P. 37(a)(5)(A).

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CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2022, the Clerk of Court was requested to file the foregoing Motion to Compel. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's electronic filing system.

/s/ Reed Brodsky
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